

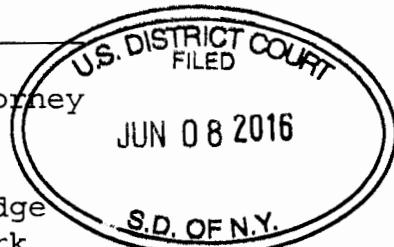
ORIGINAL DOC #

Approved:



NOAH SOLOWIEJCZYK  
Assistant United States Attorney

Before: HONORABLE KEVIN N. FOX  
United States Magistrate Judge  
Southern District of New York



**16 MAG 3629**

UNITED STATES OF AMERICA,

v.

FERNANDO SERRANO,

Defendant.

SEALED COMPLAINT

: Violations of 18  
: U.S.C. §§ 371 and 2;  
: 42 U.S.C. § 1320a-  
: 7b(b) (2) (B)

: COUNTY OF OFFENSE:  
: NEW YORK

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SOUTHERN DISTRICT OF NEW YORK, ss.:

BRUCE WAYNE, being duly sworn, deposes and says that he is a Special Agent with the Federal Bureau of Investigation ("FBI"), and charges as follows:

COUNT ONE

1. From at least in or about October 2013 up to and including in or about June 2015, in the Southern District of New York and elsewhere, FERNANDO SERRANO, the defendant, and others known and unknown, unlawfully, willfully, and knowingly did combine, conspire, confederate, and agree together and with each other to commit an offense against the United States, to wit, to violate Title 42, United States Code, Section 1320a-7b(b) (2) (B).

2. It was a part and object of the conspiracy that FERNANDO SERRANO, the defendant, and others known and unknown, unlawfully, willfully, and knowingly would and did offer and pay remuneration (including kickbacks, bribes, and rebates), directly and indirectly, overtly and covertly, in cash and in kind, to a person to induce such person to purchase, lease, order, and arrange for and recommend purchasing, leasing, and ordering a good, facility, service, and item for which payment may be made in whole and in part under a Federal health care

program, in violation of Title 42, United States Code, Section 1320a-7b(b) (2) (B).

Overt Acts

3. In furtherance of this conspiracy and to effect the illegal object thereof, the following overt acts, among others, were committed in the Southern District of New York and elsewhere:

a. On or about July 21, 2014, FERNANDO SERRANO, the defendant, in his capacity as a Specialty Sales Professional ("SSP") for a pharmaceutical company ("Pharma Company-1"), organized and attended a speaker program ("Speaker Program") at a restaurant located in Manhattan, New York. The doctor ("Doctor-1") who served as the speaker ("Speaker") for this Speaker Program received compensation from Pharma Company-1 in connection with this Speaker Program in order to induce Doctor-1 to prescribe a fentanyl-based sublingual spray manufactured by Pharma Company-1 (the "Fentanyl Spray").

b. On or about February 4, 2015, SERRANO, in his capacity as an SSP for Pharma Company-1, organized and attended a Speaker Program in Manhattan, New York. Pharma Company-1 compensated Doctor-1 in connection with this Speaker Program in order to induce Doctor-1 to prescribe the Fentanyl Spray.

(Title 18, United States Code, Section 371.)

COUNT TWO

4. From at least in or about October 2013 up to and including in or about June 2015, in the Southern District of New York and elsewhere, FERNANDO SERRANO, the defendant, willfully and knowingly offered and paid remuneration (including kickbacks, bribes, and rebates), directly and indirectly, overtly and covertly, in cash and in kind, to a person to induce such person to purchase, lease, order, and arrange for and recommend purchasing, leasing, and ordering a good, facility, service, and item for which payment may be made in whole and in part under a Federal health care program.

(Title 42, United States Code, Section 1320a-7b(b) (2) (B), and Title 18, United States Code, Section 2.)

The bases for my knowledge and the foregoing charges are, in part, as follows:

5. I am a Special Agent with the FBI currently assigned to the FBI's New York Health Care Fraud Task Force, and I have been personally involved in the investigation of this matter. This affidavit is based in part upon my conversations with law enforcement agents and witnesses, and my examination of reports and records. Because this affidavit is being submitted for the limited purpose of establishing probable cause, it does not include all of the facts that I have learned during the course of this investigation. Where the contents of documents and the actions, statements, and conversations of others are reported herein, they are reported in substance and in part, except where otherwise indicated.

**Overview of the Speaker Program Kickback Scheme**

6. As set forth in more detail below, FERNANDO SERRANO, the defendant, and others known and unknown, participated in a scheme to pay doctors, including Doctor-1, in connection with Pharma Company-1's Speaker Program in order to induce these doctors to prescribe the Fentanyl Spray. Doctors selected as Speakers by Pharma Company-1 were compensated for purportedly providing educational presentations regarding the Fentanyl Spray to a peer-level audience of healthcare professionals using a preapproved slide presentation. In reality, however, many of the Speaker Programs that SERRANO directly organized as an SSP were predominantly social gatherings at high-end restaurants that involved no education and no slide presentation.

7. Furthermore, many of the Speaker Programs FERNANDO SERRANO, the defendant, directly organized as an SSP lacked an appropriate audience of healthcare professionals. The sign-in sheets for such Speaker Programs were at times forged by SERRANO or with SERRANO's knowledge so as to make it appear that the Speaker Programs had an appropriate audience of healthcare professionals when, in truth and fact, they did not.

8. FERNANDO SERRANO, the defendant, also provided remuneration to doctors, including doctors who served as Speakers and attended Speaker Programs, that bore no relation to any educational purpose, contrary to Pharma Company-1's written policies and procedures. This illegitimate remuneration, which was in addition to the significant Speaker Program fees, included paying for alcoholic drinks for doctors.

9. At many of the Speaker Programs directly organized by FERNANDO SERRANO, the defendant, most, and in numerous instances all, of the attendees had previously been to

Speaker Programs regarding the Fentanyl Spray organized by SERRANO. Because all Speaker Programs that were legitimate required use of the same preapproved slide presentation, there was no educational purpose for a healthcare professional to attend Speaker Programs on a repeated basis.

10. FERNANDO SERRANO, the defendant, was instructed, via email and otherwise, by his District Manager ("Manager-1") to expect and demand that those doctors who were selected and compensated by Pharma Company-1 as Speakers should prescribe large quantities of the Fentanyl Spray in return. As is described in more detail below, it was well understood among Pharma Company-1 SSPs supervised by Manager-1 that doctors were selected as Speakers in order to induce these doctors to prescribe large quantities of the Fentanyl Spray.

Payments To, and Fentanyl Spray Prescriptions By, Doctor-1

11. FERNANDO SERRANO, the defendant, was the designated SSP for Doctor-1, who served as a Speaker for Pharma Company-1 during the entirety of SERRANO's employment between in or about October 2013 and in or about June 2015. As part of his responsibilities, SERRANO organized and attended Speaker Programs that were led by Doctor-1. Based on my review of publicly available data maintained by the Centers for Medicare and Medicaid Services ("CMS") regarding remuneration provided by pharmaceutical companies to doctors, I know that Doctor-1 was highly compensated by Pharma Company-1 during SERRANO's tenure as a result of Doctor-1's participation in the Speaker Program. By way of example, in 2014, Pharma Company-1 reported to CMS that it made payments of approximately \$147,245 in Speaker Program fees to Doctor-1. In 2014, Doctor-1 was one of the top recipients of Speaker Program fees from Pharma Company-1 in the entire United States.

12. Furthermore, based on my review of Medicare Part D billing records, I know that Doctor-1 was one of the top prescribers of the Fentanyl Spray in the entire United States during the time period when FERNANDO SERRANO, the defendant, was Doctor-1's designated SSP. By way of example, in 2014 Doctor-1 accounted for approximately \$1.2 million worth of prescriptions of the Fentanyl Spray that were reimbursed by Medicare, which made Doctor-1 approximately the 14th highest prescriber of the Fentanyl Spray in the United States based on Medicare Part D billing. Based on my review of records obtained from the New York State Department of Health, Bureau of Narcotics

Enforcement, as well as pricing data compiled by a major pharmacy benefit management organization in 2012 with respect to the Fentanyl Spray, I believe that in 2014, Doctor-1 prescribed over \$3 million worth of the Fentanyl Spray that was reimbursed by various private insurance companies.

Background on the Fentanyl Spray and the TIRF REMS Program

13. Based upon my training and experience, my participation in this investigation, my review of publications issued by the Drug Enforcement Administration ("DEA"), and my review of public statements issued by Pharma Company-1 and the United States Food and Drug Administration ("FDA"), I have learned, among other things, the following regarding Fentanyl and Pharma Company-1's Fentanyl Spray:

a. Fentanyl is a synthetic opioid that is classified as a Schedule II controlled substance under the Controlled Substances Act. Fentanyl is primarily utilized as a pain relief medication and is approximately 100 times more potent than morphine as an analgesic. Fentanyl can serve as a direct substitute for heroin in opioid-dependent individuals. Fentanyl is a dangerous substitute for heroin because it is much more potent and can result in frequent overdoses that can lead to respiratory depression and death.

b. In or about January 2012, the FDA approved the Fentanyl Spray manufactured by Pharma Company-1 solely for "the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain." The Fentanyl Spray is the only FDA-approved product that Pharma Company-1 currently has on the market. For 2015, Pharma Company-1 reported approximately \$330 million in net revenue from the Fentanyl Spray.

14. Based upon my training and experience, my participation in this investigation, my review of publicly available reports and records, and my review of a report prepared by a Special Agent with the United States Department of Health and Human Service, Office of Inspector General ("HHS OIG") participating in this investigation ("Agent-1"), I have learned, among other things, the following regarding the FDA's Transmucosal Instant-Release Fentanyl ("TIRF") Risk Evaluation and Management Strategy ("REMS") program (the "TIRF REMS Program") :

a. The TIRF REMS Program was established in order to "mitigate the risk of misuse, abuse, addiction, overdose, and serious complications due to medication errors by: (1) Prescribing and dispensing TIRF medicines only to appropriate patients, which includes use only in opioid-tolerant patients; (2) Preventing inappropriate conversion between TIRF medicines; (3) Preventing accidental exposure to children and others for whom it was not prescribed; and (4) Educating prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose TIRF medicines."

b. Under the TIRF REMS Program, physicians may only prescribe a TIRF drug, which includes the Fentanyl Spray, after they have enrolled in the TIRF REMS Program and completed the necessary training and testing associated with enrollment.

Pharma Company-1's Policies and Procedures Regarding Interactions With Healthcare Professionals and Speaker Programs

15. Based on my review of Pharma Company-1's Code of Conduct, which was adopted in or about 2013 (the "Code of Conduct"), and the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals (the "PhRMA Code"),<sup>1</sup> I have learned, among other things, the following:

a. Pharma Company-1 employees are prohibited from providing items that do not serve any educational purpose to healthcare professionals. Meals can be provided to healthcare professionals only if such meals are modest and provided at a location that is conducive to discussing educational information. Any meals or other items of value provided to healthcare professionals must be accurately documented by Pharma Company-1 employees.

b. Pharma Company-1 employees cannot offer anything of value to a person intended to influence that person to recommend or purchase a product or service that may be reimbursed by the federal government.

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<sup>1</sup> Pharma Company-1 expressly adopted the PhRMA Code in its Code of Conduct. Based on my review of documents obtained in connection with this investigation, I also know that the contents of the PhRMA Code were included in Pharma Company-1's training materials provided to its SSPs.

c. "[E]ntertainment or recreational benefits" should not be offered to healthcare professionals "regardless of (1) the value of the items, (2) whether the company engages the healthcare professional as a speaker or consultant, or (3) whether the entertainment or recreation is secondary to an educational purpose." Furthermore, a pharmaceutical company must "ensure that speaking arrangements are neither inducements nor rewards for prescribing a particular medicine or course of treatment" and that "decisions regarding the selection or retention of healthcare professionals as speakers should be made based on defined criteria such as general medical expertise and reputation, knowledge and experience regarding a particular therapeutic area, and communications skills."

16. During the course of this investigation, I have reviewed an internal presentation from Pharma Company-1's Medical Marketing Communications department regarding Pharma Company-1's Speaker Programs (the "Speaker Programs Presentation"), and an internal operating procedure document adopted by Pharma Company-1 in or about February 2014 relating to Pharma Company-1's Speaker Programs (the "Speaker Programs Policy"). Based on my review of the these documents, I have learned, among other things, the following:

a. The objective of the Pharma Company-1 Speaker Programs is "[p]eer-to-[p]eer on-label education of healthcare professionals." "The specific content of the [Speaker Program] is developed by [Pharma Company-1] and approved by the [Promotional Review Committee] prior to use." The Pharma Company-1 employee who organizes a Speaker Program must ensure that the Speaker uses the approved slide decks, must monitor the Speaker Program for compliance with all other relevant Pharma Company-1 policies, and must report any Speaker's non-compliance with these policies.

b. The selection of a healthcare professional as a Speaker is not to be used as inducement to prescribe. A healthcare professional must also never be engaged as a Speaker in order to "build[] a relationship with or . . . gain access to [the healthcare professional]." Speakers are to be nominated by Pharma Company-1's sales unit based on medical expertise that follows established criteria and not based on prescribing patterns, and "[a] speaker must be selected only if there is a legitimate business need."

c. Speaker Program attendees "should include appropriate healthcare providers who treat and manage patients with breakthrough cancer pain." The proper audience for a

Speaker Program "should be peer-level and not direct subordinates of [the] Speaker," and spouses and other guests are generally not permitted to attend Speaker Programs. Moreover, "[t]here must be at least two or more [healthcare professionals] in attendance" at a Speaker Program, and "[i]f there are fewer than two confirmed attendees, three full business days or more prior to the event, [Pharma Company-1] must cancel the event."

d. Pharma Company-1 Speaker Programs must occur at locations that are conducive to the exchange of information. All meals provided at Speaker Programs must be at most "\$125 per person (includes meal, beverage, tax and gratuity," and "alcohol provided at such events should not be in excess."

e. At the beginning and end of Speaker Programs, the Pharma Company-1 employee who organized the event must ensure that all attendees have legibly completed the sign-in sheet.

17. During the course of this investigation, I have reviewed certain Pharma Company-1 employee training materials relating to the area of compliance (the "Training Materials"). Based on my review of the Training Materials, I have learned, among other things, that Pharma Company-1 employees received training regarding the prohibitions on providing illegal kickbacks to healthcare professionals. The Training Materials specifically state that "under the anti-kickback statute, neither a legitimate purpose for an arrangement (e.g., physician education), nor a fair market value payment, will necessarily protect remuneration if there is also an illegal purpose (i.e., the purposeful inducement of business)."

18. Based on my participation in this investigation, I have learned that in order to serve as a Speaker for Pharma Company-1, a doctor would enter into a formal written Speaker Agreement with Pharma Company-1. Based on my review of the Speaker Agreement executed by Doctor-1 and Pharma Company-1 in or about March 2014 (the "Speaker Agreement"), I have learned, among other things, the following:

a. Under the Speaker Agreement, the "Speaker agrees to educate a selected target audience in venues consistent with industry and company policies." Furthermore, the Speaker Agreement states that "[e]ach speaker will be requested, based on their availability, to present pre-approved program slides consistent with labels of [Pharma Company-1] products, therapeutic category, clinical best practices and/or disease state awareness."

b. The Speaker Agreement entered into between Pharma Company-1 and Doctor-1 in or about March 2014 further specifies that Doctor-1 will receive \$3,000 as compensation for each in-person Speaker Program completed by Doctor-1.

SERRANO Was Instructed By Manager-1 to Expect and Demand That Speakers Prescribe Large Quantities of the Fentanyl Spray

19. Based on my review of email communications obtained during the course of this investigation, as well as my participation in interviews of former Pharma Company-1 SSPs who were supervised by Manager-1, I have learned that Manager-1 instructed SSPs, including FERNANDO SERRANO, the defendant, to expect and demand that those doctors who were selected as Speakers prescribe large quantities of the Fentanyl Spray in return.

20. Based on my review of electronic communications between Pharma Company-1 employees obtained during the course of this investigation, I have learned, among other things the following:

a. On or about March 28, 2014, Manager-1 sent an email to various SSPs that Manager-1 supervised, including FERNANDO SERRANO, the defendant, with the subject heading "END IS NEAR....," that stated, in substance and in part, the following:

NYC,

Good luck today, biggest Friday of the quarter is here!! Still 4 days including today to get RXs filled, put more \$\$ in your pockets and for those of you who haven't met your baseline as of yet, there's still time left! You have all heard it before, LIVE WITH YOUR TOP DOCS, and even more importantly ASK for their business.

We all benefit from having the best ROO [Rapid-Onset Opiod] in its class, that being said, there is no excuse for any of your docs to not take care of you at this crucial time of the quarter. For the first time as a company, we are facing the challenge of meeting our quarterly goal. That being said, its time for all of your your [sic] top prescribers (esp. SPEAKERS) to give back for all of the hard work, long days and late nights you have spoiled them with. Keep pushing as hard as you all possibly can and remember why today is

especially most important being that it will set you up for a few hopeful RXs sat/sun and a HUGE Monday!!!

. . . .

b. On or about February 20, 2014, Manager-1 sent an email to various SSPs that Manager-1 supervised, including SERRANO, that stated, in substance and in part, the following:

NYC,

Everyone on this team has stepped it up the past week or so. I am extremely proud and optimistic at the movement that has been going on. We MUST keep pushing as hard as we can to get every SSP apart of this team on the board daily! NOW is the time to attain as many RXs as possible going into the NSM [National Sales Meeting]. NYC needs to go into this meeting on fire, and show our entire company that we belong in the top 3 nationally, and aren't just carried by one or two reps.

One week until [National Sales Meeting], and I need everyone on this team to work their relationships. Ask each of your top prescribers to do whatever they can to make you look like an absolute superstar for the next week, especially while we are [at the National Sales Meeting]. This is what reps work all year for, do not be hesitant in asking your docs to give you the business in which you are owed, deserve, and will help in making you shine at [the National Sales Meeting]. Show everyone at [Pharma Company-1] that your time has been well spent and the formula has been followed. All of the breakfasts, lunches, ISPs [Speaker Programs], and top customer service to go along with helping provide your docs pts with the best ROO [Rapid-Onset Opioid] product in its class for treating BTCP [breakthrough cancer pain]. This has to be reciprocated to you for all of your hard work! If you have a relationship, asking this of your docs should be one of the easiest things you do as an SSP. You all have claimed to have relationships so this should not be a problem. If you feel that you cannot complete this simple task with the most positive results, then there is no point in attending [the National Sales Meeting].

. . . .

Thanks in advance for all of your efforts, and I ask all of you to please ENSURE that we have the best week of sales we have ever had as a team. The time is now!!

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SERRANO Organized Sham Speaker Programs, Provided Other Illegitimate Remuneration to Speakers and Speaker Program Attendees, and Forged Sign-In Sheets

21. As part of this investigation, I have participated in an interview of a doctor ("CW-1")<sup>2</sup> who, based on my review of sign-in sheets from Speaker Programs, I know was listed as an attendee at numerous Speaker Programs organized by FERNANDO SERRANO, the defendant, and led by Doctor-1. Based on my participation in the interview of CW-1, I have learned, among other things, the following:

a. CW-1 is a doctor who first met SERRANO when SERRANO did a sales call at CW-1's office to promote the Fentanyl Spray. In or about 2014, after making multiple visits at CW-1's office, SERRANO eventually invited CW-1 to Speaker Programs that SERRANO organized at various restaurants in Manhattan, New York.

b. CW-1 attended Pharma Company-1 Speaker Programs approximately twice per month. All of these Speaker Programs that CW-1 attended were organized by SERRANO. CW-1 identified Doctor-1 as the Speaker at the vast majority of the Speaker Programs that CW-1 attended.

c. The Pharma Company-1 Speaker Programs organized by SERRANO were informal social gatherings, according to CW-1. No education regarding the Fentanyl Spray occurred at

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<sup>2</sup> CW-1 is currently serving a prison sentence for unrelated federal offenses in the District of New Jersey. CW-1 has provided information to the Government in connection with this investigation in the hopes of obtaining a reduction in CW-1's current sentence. Information provided by CW-1 has been corroborated by other evidence, including, but not limited to, sign-in sheets from Speaker Programs, interviews with former employees of Pharma Company-1, and interviews with other attendees of Speaker Programs.

virtually all of the Speaker Programs that CW-1 attended. There was no audiovisual equipment utilized at the Speaker Programs, no formal presentation regarding the Fentanyl Spray and, except for one occasion, no slide presentation regarding the Fentanyl Spray. Neither SERRANO nor the Speaker would typically provide a formal introduction to the Speaker Programs, and attendees would often arrive late and order food and drinks after they arrived.

d. Attendees at the Speaker Programs could order as many alcoholic beverages of any type that they chose. CW-1 recalled the attendees at one Speaker Program doing shots of liquor together.<sup>3</sup>

e. The attendees of the Speaker Programs, including Doctor-1 and SERRANO, would frequently go out to a bar for alcoholic beverages after the Speaker Program had concluded. CW-1 recalled at least two instances when CW-1 went out with SERRANO and other Speaker Program attendees socially after Speaker Programs. On one occasion, the attendees, including SERRANO and Doctor-1, went to a bar in Manhattan, New York and the group ordered alcoholic beverages, which CW-1 believed SERRANO paid for. On another occasion, many of the attendees of the Speaker Program, including CW-1, but not Doctor-1, went to a strip club ("Strip Club-1") together after the Speaker Program had concluded. CW-1 and the other attendees did not have to pay a cover charge when they entered Strip Club-1. CW-1 and the other attendees were then led to a private table where bottles of alcohol were provided. CW-1 did not pay for the alcohol that CW-1 consumed at Strip Club-1.

f. During one of the Speaker Programs that CW-1 attended, Doctor-1 stated to CW-1, in substance and in part, that Doctor-1 had heard CW-1 was not prescribing the Fentanyl Spray. CW-1 stated in response, in substance and in part, that CW-1 did not have many cancer patients that needed the Fentanyl Spray. During this conversation, Doctor-1 informed CW-1 that Doctor-1 had written approximately 300 to 500 prescriptions of the Fentanyl Spray. CW-1 was surprised to learn that Doctor-1 had written so many prescriptions for the Fentanyl Spray given that Doctor-1 was not an oncologist.

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<sup>3</sup> I have reviewed certain receipts associated with Speaker Programs attended by CW-1 and organized by SERRANO, which corroborate that any type of alcoholic beverage could be ordered by attendees at Speaker Programs organized by SERRANO and that hard liquor was ordered at Speaker Programs.

g. SERRANO told CW-1, in substance and in part, that CW-1 needed to help SERRANO out by writing prescriptions of the Fentanyl Spray.

h. On numerous occasions, SERRANO put CW-1's name on sign-in sheets as an attendee for Speaker Programs that CW-1 had not actually attended. On certain occasions, SERRANO informed CW-1 that SERRANO was putting CW-1's name on a sign-in sheet for a Speaker Program that CW-1 did not attend. SERRANO also occasionally came to CW-1's office and asked CW-1 to sign sign-in sheets for Speaker Programs that CW-1 knew CW-1 had not attended. CW-1 assented to SERRANO's requests and signed these sign-in sheets.

i. During the interview of CW-1, law enforcement showed CW-1 approximately 10 sign-in sheets from Speaker Programs organized by SERRANO that reflected that CW-1 had purportedly attended these events. After reviewing these sign-in sheets, CW-1 identified multiple sign-in sheets that contained forged versions of CW-1's signature.<sup>4</sup>

22. As part of this investigation, I have participated in an interview of a doctor ("Doctor-2") who, based on my review of a sign-in sheet from a Speaker Program, I know was listed as an attendee at a Speaker Program organized by FERNANDO SERRANO, the defendant. Based on my participation in the interview of Doctor-2, I have learned, among other things, the following:

a. Doctor-2 is board certified in internal medicine. Doctor-2 previously worked for CW-1 at one time.

b. Doctor-2 had never heard of Pharma Company-1 or the Fentanyl Spray.

c. During the interview, Doctor-2 was shown a sign-in sheet for a Speaker Program that occurred on or about June 3, 2014, which listed Doctor-2 as an attendee and purportedly contained Doctor-2's signature. After reviewing the sign-in sheet for this Speaker Program, Doctor-2 stated, in

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<sup>4</sup>I have compared the signatures on certain of the Speaker Program sign-in sheets that CW-1 identified as containing forged versions of CW-1's signature with the signatures on the Speaker Program sign-in sheets that CW-1 identified as containing CW-1's actual signature, and these signatures do not appear to match.

substance and in part, that Doctor-2 was certain that the signature on the sign-in sheet was not Doctor-2's true signature. Doctor-2 also noted that the State License Number filled in under Doctor-2's name on the sign-in sheet was incorrect.<sup>5</sup> On the June 3, 2014 Speaker Program sign-in sheet, FERNANDO SERRANO, the defendant, is listed as the SSP who organized the Speaker Program, and Doctor-1 is listed as the designated Speaker.<sup>6</sup>

23. As part of this investigation, I participated in an interview of a former SSP at Pharma Company-1 ("CW-2").<sup>7</sup> Based on my participation in the interview of CW-2, I have learned, among other things, the following:

a. In or about February 2015, CW-2 attended a Speaker Program at a restaurant in Manhattan, New York that was organized by FERNANDO SERRANO, the defendant, and led by Doctor-1. At this Speaker Program, Doctor-1 did not use the preapproved slide presentation or give any other formal presentation regarding the Fentanyl Spray. This Speaker Program was predominantly a social gathering. Manager-1 was also in attendance for this Speaker Program. During the Speaker Program, SERRANO invited CW-2 and another doctor ("Doctor-3") out for a drink after the Speaker Program was over.

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<sup>5</sup> Based on my review of publicly available sources, I have confirmed that Doctor-2's New York State Medical License Number is incorrectly filled in on the sign-in sheet for the June 3, 2014 Speaker Program.

<sup>6</sup> Based on my participation in this investigation, I know that the SSP who organizes a Speaker Program - in this case SERRANO - is responsible for obtaining signatures from Speaker Program attendees and for submitting the completed sign-in sheet to Pharma Company-1.

<sup>7</sup> CW-2 is assisting with the Government's investigation in the hopes of not being charged criminally in connection with CW-2's conduct while employed at Pharma Company-1. Information provided by CW-2 has been corroborated by other evidence, including, but not limited to, sign-in sheets from Speaker Programs, email and text message communications obtained during the course of this investigation, and interviews with other former employees of Pharma Company-1.

b. A sign-in sheet for the February 2015 Speaker Program reflected that Doctor-1, Doctor-3, and another doctor ("Doctor-4") had attended this Speaker Program. After reviewing the sign-in sheet for the February 2015 Speaker Program, CW-2 stated, in substance and in part, that CW-2 believed that only two doctors had been in attendance - Doctor-1 and Doctor-3 - and that the sign-in sheet, which reflected that Doctor-4 had attended the Speaker Program, appeared to be inaccurate.<sup>8</sup>

c. After SERRANO was terminated by Pharma Company-1, CW-2 spoke with SERRANO by phone and learned that SERRANO was fired for having too many repeat attendees at the Speaker Programs that SERRANO organized.

24. As part of this investigation, I participated in interviews of a former SSP at Pharma Company-1 ("CW-3").<sup>9</sup> From my participation in the interviews of CW-3, I have learned, among other things, the following:

a. Prior to being hired as an SSP by Pharma Company-1, CW-3 attended a Speaker Program with FERNANDO SERRANO, the defendant, and Manager-1, among others, at a restaurant in Manhattan, New York during which the designated Speaker ("Doctor-5") did not utilize the preapproved slide presentation. Following this Speaker Program, SERRANO, Doctor-5, Manager-1, CW-3, and others went to Strip Club-1 together. At Strip Club-1, the group was joined by another doctor ("Doctor-6"), who subsequently became a Speaker for Pharma Company-1. Bottles of alcohol on a reserved table were provided for the group at Strip Club-1. CW-3 did not pay for the alcohol CW-3 consumed or any cover charge while at Strip Club-1.

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<sup>8</sup> I have compared the purported signature for Doctor-4 from the sign-in sheet for the February 2015 Speaker Program with the signature for Doctor-4 from an October 28, 2014 Speaker Program sign-in sheet, and these signatures do not appear to match.

<sup>9</sup> CW-3 is assisting with the Government's investigation in the hopes of not being charged criminally in connection with CW-3's conduct while employed at Pharma Company-1. Information provided by CW-3 has been corroborated by other evidence, including, but not limited to, sign-in sheets from Speaker Programs, email and text message communications obtained during the course of this investigation, and interviews with other former employees of Pharma Company-1.

b. SERRANO and Doctor-5 would go out drinking together after Speaker Programs.

c. At some point after CW-3 had been hired as an SSP, CW-3 attended a Speaker Program at a restaurant in Manhattan, New York organized by SERRANO and led by Doctor-1. This Speaker Program was mostly a social event. CW-3 did not recall any formal presentation with respect to the Fentanyl Spray occurring at this Speaker Program.

d. CW-3 had heard from Manager-1, who was CW-3's and SERRANO's supervisor, that SERRANO had brought strippers to Speaker Programs.

e. SERRANO had been Doctor-5's designated SSP immediately prior to CW-3. When CW-3 became the designated SSP for Doctor-5 in or about January 2014, CW-3 quickly learned that Doctor-5 did not use the preapproved slide presentation at the Speaker Programs that Doctor-5 led. CW-3 estimated that only approximately thirty percent of Doctor-5's Speaker Programs were legitimate educational events, and that the remaining seventy percent were merely social dinners without any educational component.

f. Repeat attendees were common at Speaker Programs because it was extremely difficult to have new attendees at every Speaker Program given the frequency with which Speaker Programs were held. Because the slide presentation was required to be the same at every legitimate Speaker Program, there was no reason, from an educational perspective, to attend Speaker Programs on a repeated basis.

**SERRANO Frequently Organized Speaker Programs With Repeat Attendees**

25. Based on my review of Speaker Program sign-in sheets obtained during the course of this investigation, I have determined that FERNANDO SERRANO, the defendant, organized numerous Speaker Programs where all of the listed attendees had previously attended Speaker Programs organized by SERRANO. As stated above, because all Speaker Programs that were legitimate required use of the same preapproved slide presentation, there was no educational purpose for a healthcare professional to attend Speaker Programs on a repeated basis. Certain examples of these Speaker Programs are described below:

a. A sign-in sheet for a Speaker Program that occurred on September 8, 2014, reflects that SERRANO was the SSP

for this Speaker Program and that Doctor-1 was the Speaker. The other attendees listed on the sign-in sheet for this Speaker Program, other than Pharma Company-1 employees, are (1) a doctor ("Doctor-7"), and (2) a pharmacist ("Pharmacist-1"). According to sign-in sheets from other Speaker Programs, prior to the September 8, 2014 Speaker Program, Doctor-7 was listed as attending at least 6 prior Speaker Programs organized by SERRANO, and Pharmacist-1 was listed as attending at least 10 prior Speaker Programs organized by SERRANO. Based on my review of other sign-in sheets from prior to September 8, 2014, I further know that Doctor-7 is listed as previously attending a Speaker Program organized by SERRANO and led by Doctor-1 as recently as August 28, 2014, and that Pharmacist-1 is listed as previously attending a Speaker Program organized by SERRANO and led by Doctor-1 as recently as August 26, 2014.

b. A sign-in sheet for a Speaker Program that occurred on October 16, 2014, reflects that SERRANO was the SSP for this Speaker Program and that Doctor-1 was the Speaker. The other attendees listed on the sign-in sheet for this Speaker Program, other than Pharma Company-1 employees, are (1) Doctor-7, (2) a pharmacist ("Pharmacist-2"), (3) Pharmacist-1, (4) CW-1, (5) another doctor ("Doctor-8")<sup>10</sup>, and (6) a registered nurse ("RN-1"). According to sign-in sheets from other Speaker Programs, prior to the October 16, 2014 Speaker Program, Doctor-7 was listed as attending at least 9 prior Speaker Programs organized by SERRANO, Pharmacist-1 was listed as attending at least 14 prior Speaker Programs organized by SERRANO, Pharmacist-2 was listed as attending at least 3 prior Speaker Programs organized by SERRANO, CW-1 was listed as attending at least 14 prior Speaker Programs organized by SERRANO, Doctor-8 was listed as attending at least 11 prior Speaker Programs organized by SERRANO, and RN-1 was listed as attending at least 8 prior Speaker Programs organized by SERRANO.

c. A sign-in sheet for a Speaker Program that occurred on February 25, 2015, reflects that SERRANO was the SSP for this Speaker Program and that Doctor-1 was the Speaker. The other attendees listed on the sign-in sheet for this Speaker Program, other than Pharma Company-1 employees, are two doctors ("Doctor-9" and "Doctor-10"), and a pharmacist ("Pharmacist-3").

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<sup>10</sup> Based on my review of documents obtained during the course of this investigation relating to the Pharma Company-1 Speaker Program, I know that, at the time that Doctor-8 attended this Speaker Program, Doctor-8 was already a Speaker for Pharma Company-1 and that SERRANO was Doctor-8's designated SSP.

According to sign-in sheets from other Speaker Programs, prior to the February 25, 2015 Speaker Program, Doctor-9 was listed as attending at least 14 prior Speaker Programs organized by SERRANO, Doctor-10 was listed as attending at least 1 prior Speaker Program organized by SERRANO, and Pharmacist-3 was listed as attending at least 25 prior Speaker Programs organized by SERRANO.

d. A sign-in sheet for a Speaker Program that occurred on April 16, 2015, reflects that SERRANO was the SSP for this Speaker Program and that Doctor-1 was the Speaker. The other attendees listed on the sign-in sheet for this Speaker Program, other than Pharma Company-1 employees, are a doctor ("Doctor-11"), Pharmacist-3, and Pharmacist-1. According to sign-in sheets from other Speaker Programs, prior to the April 16, 2015 Speaker Program, Doctor-11 was listed as attending at least 6 prior Speaker Programs organized by SERRANO, Pharmacist-3 was listed as attending at least 27 prior Speaker Programs organized by SERRANO, and Pharmacist-1 was listed as attending at least 20 prior Speaker Programs organized by SERRANO.

SERRANO's Compensation At Pharma Company-1

26. Based on my review of documents obtained during the course of this investigation relating to compensation of the Pharma Company-1 sales force, I have learned, among other things, that FERNANDO SERRANO, the defendant, received quarterly bonuses that were based on Pharma Company-1's incentive-based compensation system. Under this incentive-based compensation system, SERRANO and other SSPs received a bonus based in large part on the volume of prescriptions from the doctors to which these SSPs were assigned. By way of example, SERRANO received a bonus of approximately \$70,000 in the first quarter of 2014, which was the 8th largest bonus paid to an SSP at Pharma Company-1 in the United States for that quarter. In the fourth quarter of 2013, SERRANO received a bonus of approximately \$100,000, which was one of the 5 largest bonuses paid to an SSP at Pharma Company-1 in the United States for that quarter.

WHEREFORE, the deponent respectfully requests that a warrant issue for the arrest of FERNANDO SERRANO, the defendant, and that he be arrested and imprisoned, or bailed, as the case may be.



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BRUCE WAYNE  
Special Agent  
Federal Bureau of Investigation

Sworn to before me this  
8th day of June, 2016

Kevin Nathaniel Fox  
THE HONORABLE KEVIN N. FOX  
UNITED STATES MAGISTRATE JUDGE  
SOUTHERN DISTRICT OF NEW YORK